



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

CHARTER

SECRETARY'S ADVISORY COMMITTEE ON HUMAN RESEARCH PROTECTIONS

AUTHORITY

The Secretary's Advisory Committee on Human Research Protections (SACHRP) is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service (PHS) Act, as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Secretary is responsible for regulatory oversight of the system for the protection of human subjects in biomedical and behavioral research supported or conducted by the Department of Health and Human Services (HHS). SACHRP shall provide expert advice and recommendations to the Secretary, through the Assistant Secretary for Health (ASH), on issues and topics pertaining to or associated with the protection of human research subjects. The Committee will work to advise the Secretary on how to improve the quality of the system of human research protection programs, including the responsibilities of investigators, institutional review boards (IRBs), administrators, and institutional officials, and the role of the Office for Human Research Protections and other offices within HHS.

DESCRIPTION OF DUTIES

The Committee shall advise, consult with, and make recommendations on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. Specifically, examples include but are not limited to advice relating to the responsible conduct of research involving human subjects with particular emphasis on:

- Special populations, such as neonates and children, prisoners, and the decisionally impaired;
- Pregnant women, embryos, and fetuses;
- Individuals and populations in international studies;
- Populations in which there are individually identifiable samples, data, or information; and
- Investigator conflicts of interest.

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In addition, the Committee shall be responsible for reviewing selected ongoing work and planned activities of the Office for Human Research Protections (OHRP) and other offices/agencies within HHS responsible for human subjects protection. These evaluations may include but are not limited to a review of assurance systems, the application of minimal research risk standards, the granting of waivers, education programs sponsored by OHRP, and the ongoing monitoring and oversight of IRBs and the institutions that sponsor research.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Committee shall provide expert advice and recommendations to the Secretary, through the Assistant Secretary for Health.

SUPPORT

Management and support services for Committee operations and activities shall be provided by OHRP, which is a program office in the Office of the Assistant Secretary for Health (OASH). OASH is a staff division in Office of the Secretary in HHS.

ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

The estimated annual cost for operating the Committee, including the approved compensation and reimbursement of travel expenses and per diem for the members, but excluding staff support is \$264,150. The estimate of annual person-years of staff support required is 1.0, at an estimated annual cost of \$140,000.

DESIGNATED FEDERAL OFFICER (DFO)

The DFO for the Committee will be selected by the ASH from among full-time or permanent part-time senior level staff within the Office for Human Research Protections. In the event that the designated official cannot fulfill the assigned responsibilities for the Committee, then the Assistant Secretary for Health or designee shall select another qualified permanent full-time or part-time senior level staff person from among staff within the OASH to permanently and/or temporarily carry out the assigned duties.

The DFO will schedule and approve all meetings of the Committee and any respective subcommittees that are to be held. The DFO will prepare and approve all meeting agendas. Development of the meeting agenda can be done in collaboration with the Committee Chair, and, when it is deemed to be appropriate, the chairs of any respective subcommittees of the Committee also can be consulted. The DFO or designee will attend all meetings of the Committee and any respective subcommittees. The DFO also has authority to adjourn meetings, when it is determined to be in the public interest, and can be directed by the Assistant Secretary for Health or designee to chair meetings of the Committee.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

The Committee will meet not less than two times a year. Meetings will be open to the public, except as determined otherwise by the Secretary or other official to whom authority has been delegated, in keeping with the guidelines under Government in the Sunshine Act, 5 U.S.C. 552b(c). The public will be given notification about all meetings that are scheduled to be held; notices to announce the meetings will be published in the *Federal Register*. Meetings will be conducted and records of the proceedings will be kept, as required by applicable laws and departmental policies. A quorum of the membership is required for the Committee to meet to conduct business; a quorum shall consist of no less than half of the voting members.

When it is determined by the Secretary, or other official to whom authority has been delegated, that a meeting will be closed or partially closed to the public, in accordance with stipulations of the Government in the Sunshine Act, 5 U.S.C. 552b(c), then a report will be prepared that includes, at a minimum, a list of the members and their business addresses, the Committee's functions, date and place of the meeting, and a summary of the Committee's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

DURATION

Continuing. There is a continuing need for the advice and recommendations provided by the Committee.

TERMINATION

Unless renewed by appropriate action, SACHRP will be terminated two years from the date this charter is filed.

MEMBERSHIP AND DESIGNATION

The Committee shall consist of eleven (11) voting public members, including the Chair, who shall be appointed by the Secretary or designee. The members shall be selected from among individuals possessing demonstrated experience and expertise in any of the several disciplines and fields pertinent to human subjects protection and/or clinical research. All public members of the Committee are classified as special government employees (SGEs) and are subject to government ethics rules.

The Committee membership shall include non-voting *ex-officio* representation from the following HHS agencies: Agency for Healthcare Research and Quality (AHRQ); Centers for Disease Control and Prevention (CDC); Food and Drug Administration (FDA); Health Resources and Services Administration (HRSA), Indian Health Service (IHS), Office for Civil Rights (OCR), and National Institutes of Health (NIH). The Committee structure also shall include non-voting *ex-officio* representation from the following 17 Federal departments/agencies that subscribe to the "Federal Policy for the Protection of Human Subjects" (referred to as the Common Rule): Department of Agriculture, Department of Commerce, Department of Defense, Department of Education, Department of Energy, Department of Homeland Security, Department of Housing and Urban Development, Department of Justice, Department of Transportation, Department of

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Veterans Affairs, Environmental Protection Agency, Social Security Administration, Agency for International Development, Central Intelligence Agency, Consumer Product Safety Commission, National Aeronautics and Space Administration, and National Science Foundation. Other federal departments/agencies shall be invited to participate as non-voting *ex officio* members, as it is deemed necessary by the Secretary or designee to effectively carry out the Committee's function.

The voting Committee members shall be appointed to serve for overlapping terms of up to four years. Terms of more than two years are contingent upon renewal of the Committee's charter by appropriate action prior to its expiration. Any member appointed to fill a vacancy for an unexpired term shall be appointed only for the remainder of that term. A member may serve no more than 180 days after the expiration of the member's term if a successor has not taken office.

SUBCOMMITTEES

In carrying out its function, the Committee may establish subcommittees composed of members of the parent committee and seek advice from non-member special consultants, with the approval of the Secretary or designee. The advice of a subcommittee shall be reported to the parent committee. The Committee will discuss the findings of a subcommittee at a public meeting, at which time the full committee will determine the appropriate action to be taken.

The Department Committee Management Officer will be notified upon establishment of each subcommittee, and will be provided information regarding name of the subcommittee, function, membership, and estimated frequency of meetings.

RECORDKEEPING

Records of the Committee and any established subcommittee will be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records or other approved agency records disposition schedule. Applicable records will be made available to the public for inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

FILING DATE:

October 1, 2016

APPROVED:

SEP 30 2016

Date


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